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**Face masks reduce the release of *Pseudomonas aeruginosa* cough aerosols when worn for clinically-relevant time periods**

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## Abstract

**Introduction:** The cystic fibrosis (CF) infection control guidelines recommend that people with CF wear face-masks when in communal areas of hospitals. Recently, we reported short-term wear of face-masks (~10-minutes) reduced the release of *Pseudomonas aeruginosa* aerosols during coughing. However, there is limited evidence to determine if face-masks continue to be effective at reducing the release of infectious cough aerosols after longer wear times. **Methods:** We recruited 25 people with CF and chronic *P. aeruginosa* infection and 10 healthy volunteers. All participants underwent up to 5 cough tests in a validated cough rig: 1) uncovered cough; 2) coughing with surgical mask worn for 10-minutes; 3) coughing with surgical mask worn for 20-minutes; 4) coughing with a surgical mask worn for 40-minutes; 5) coughing with an N95 respirator worn for 20-minutes (optional). The wear time of the mask included a 5-minute cough period in the aerosol collection rig. Sputum samples and cough aerosols were collected from participants with CF as previously described. All participants rated their level of comfort post-test. **Results:** Surgical masks and N95 respirators were effective at reducing the release of *P. aeruginosa* aerosols during coughing after 40-minutes total wear and 20-minutes total wear respectively. Both participants with CF and healthy volunteers rated the surgical masks as more comfortable compared to N95 respirators. **Conclusions:** Surgical masks were the preferred interface to wear as source control and were effective at reducing the release of *P. aeruginosa* aerosols during coughing after 40-minutes of total wear.

## Introduction

Aerosol dissemination of respiratory pathogens may contribute to person-to-person transmission in people with cystic fibrosis (CF) [1]. This evolving knowledge of transmission modes has led to an update of the CF Foundation Infection and Prevention Control Guidelines recommending people with CF wear surgical masks in communal hospital areas to prevent the spread of CF respiratory pathogens [2]. These guidelines recommended the use of surgical masks as source control despite limited evidence for this application.

We recently demonstrated that short-term wear of face-masks (10-minutes total wear) significantly reduces the release of *Pseudomonas aeruginosa* aerosols during coughing in people with CF [3]. These findings are consistent with an earlier study of people with CF that reached the same conclusion after very short-term wear of surgical masks (worn for 21 coughs) [4]. These results and a recent editorial to our short-term mask wear study [5] support our current aim to investigate the effectiveness, tolerability and functionality of face-masks as source control after extended wear.

## Methods

We recruited 25 people with CF and chronic *P. aeruginosa* infection [6] from the Adult Cystic Fibrosis Centre, The Prince Charles Hospital, Brisbane, Australia. Ten healthy volunteers were recruited from hospital and research staff to assess mask comfort and mask weight change. All participants performed up to five randomly ordered tests in a validated cough system [7]: 1) uncovered cough; 2) coughing with surgical mask worn for 10-minutes; 3) coughing with surgical mask worn for 20-minutes; 4) coughing with surgical mask worn for 40-minutes; 5) coughing with N95 mask worn for 20-minutes [3, 7]. The N95 test was an optional test based on the poor comfort ratings observed in our earlier mask study [3].

The duration of the mask wear tests were selected based on observation of patients moving around communal areas of the hospital described here. Two types of masks were tested: “surgical mask” [Catalogue # 47107; Halyard FLUIDSHIELD Level 3 Fog-Free Procedure Mask ( $\Delta P < 2.5$ ), Georgia, USA] and “N95 mask” [Catalogue # 46827 (small) or 46727 (regular), Halyard FLUIDSHIELD N95 Particulate Filter Respirator and Surgical Mask, Georgia, USA]. New masks were used for each test. The total wear time of the masks included 1-minute positioning of the participant into the rig, 2-minutes of tidal breathing with HEPA-filtered air, a 5-minute cough period, followed by another 2-minutes of tidal breathing. Cough aerosol collection, sputum processing and *P. aeruginosa* genotyping were performed as previously described [1, 3, 8]. All participants rated their comfort levels after each test [3, 9]. All masks were weighed before and following each test.

SPSS version 25 was used for statistical analysis. Participants with CF were stratified by the amount of aerosol colony forming units (CFU) produced during the uncovered cough test: high producer (total CFU was  $\geq 10$ ) or no/low producer (total CFU was  $< 10$ ) [3]. Categorical variables were examined using Pearson Chi-squared test or Fisher’s Exact test. Continuous variables were examined using a Student t-test or Mann-Whitney U test. CFU were log transformed and the paired t-test examined changes over time. The McNemar-Bowker test was used to examine comfort scores over time. The Wilcoxon Signed Rank Test was used to examine the change in mask weight over time.

## Results

*P. aeruginosa* was cultured from the sputum of 25/25 participants with CF and was cultured in cough aerosols during the uncovered cough test of 20/25 participants (Table 1). *P. aeruginosa*

was cultured from cough aerosols of 9/20 participants during any of the surgical mask tests (10-minutes, 20-minutes and 40-minutes total wear time) and 4/20 participants during the N95 mask test of 20-minutes total wear. The CFU were significantly reduced for the surgical mask tests compared with the uncovered cough test ( $p<0.001$ ). Between mask tests, the CFU count remained similar as the duration of surgical mask wear increased as well as between mask types (Table 1). The *P. aeruginosa* strain types found in the cough aerosols were genetically indistinguishable from the paired sputum sample of each participant.

Participants with CF rated surgical masks less comfortable than healthy volunteers for all test durations (surgical mask: 10-minutes,  $p=0.001$ ; 20-minutes,  $p=0.007$ ; 40-minutes,  $p=0.023$ ; N95: 20-minutes,  $p=0.018$ ) (Table 2). Participants with CF were more tolerant of surgical mask wear (good comfort) after 10- and 20-minutes total wear time if they had higher lung function, yet this difference was lost after 40-minutes of surgical mask wear. N95 masks were rated less comfortable in both participants with CF and healthy volunteers (Table 2).

The change in mask weight for each test ranged from no weight change to a maximum weight change of 0.02g and was comparable between participants with CF and healthy volunteers (Table 2). There was a minor increase in surgical mask weight (median change, 0.01g) after 40-minutes compared with 10-minutes wear ( $p=0.031$ ) (Table 2). No statistical differences in mask weight change were seen in other time or mask type comparisons (Table 2).

## Discussion

Our study demonstrates that face masks worn for clinically-relevant time periods are effective at reducing the release of potentially infectious aerosols during coughing in people with CF. These results extend upon our earlier observations that demonstrated surgical masks and N95



156 masks were both effective at reducing the release of infectious cough aerosols when the mask  
157 wear was of shorter duration [3]. The outcomes of our studies demonstrate that surgical masks  
158 are effective and tolerable as source control [3] and support the CF Foundation (USA)  
159 recommendations for surgical mask wear to reduce the risk of CF pathogen transmission in the  
160 hospital setting [2].

161  
162 Surgical masks were the preferred mask type for source control in terms of comfort, which is  
163 similar to our short-term wear mask study findings [3]. Healthy volunteers tolerated the surgical  
164 masks better than those with CF and participants with CF who had higher lung function  
165 tolerated surgical masks better. When the comfort of surgical masks was assessed after extended  
166 wear in this cohort, a major finding was that the comfort ratings remained unchanged regardless  
167 of wear time for both people with and without CF. Therefore, surgical masks are not only  
168 effective but are also well tolerated by participants after 40-minutes total wear.

169  
170 An accompanying editorial of our recent mask study [3] questioned if mask dampness may  
171 affect the ability of the mask to function as source control after prolonged wear times [5]. The  
172 CF infection control guidelines indicate that masks being used as source control should be  
173 replaced when damp [2] and excessive moisture accumulation was a common reason for  
174 surgical mask replacement in people with tuberculosis using surgical masks as source control  
175 [10]. Our data indicates that although there was evidence of surgical mask moisture  
176 accumulation after 40-minutes total wear (estimated by increased weight), the surgical mask  
177 continued to function effectively as source control mitigating this concern.

178  
179 There are several limitations to this study: 1) The infectious dose of *P. aeruginosa* is unknown  
180 and therefore the infection risk cannot be determined; 2) Participants remained in view of staff

181 while wearing the masks and this may have modified the extent to which participants interfered  
182 with the mask leading to an incorrect estimation on the masks protective effects; 3) Participants  
183 were seated during the cough testing and this may have impacted on the participant's ability to  
184 cough freely; 4) While some participants experienced episodes of spontaneous cough during  
185 testing, we were unable to differentiate between spontaneous and voluntary cough. Therefore,  
186 the protective effects of the masks may be overestimated; 5) The effectiveness and tolerability  
187 of masks is reported in adults only and these characteristics need to be studied in children; 6)  
188 Our study had a maximum wear time of 40-minutes and the effectiveness of masks worn for  
189 longer periods is unknown; 7) We did not assess inward protection provided by masks but this  
190 has been highlighted as an understudied field of research [11].

191  
192 Our study confirms the effectiveness of surgical masks at reducing the release of *P. aeruginosa*  
193 cough aerosols in people with CF and provides evidence of patient tolerability and functionality  
194 of these masks as source control after 40-minutes of total wear.

195  
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200 the study for supporting the work.

202 Table 1: Demographic and clinical characteristics of the study participants

	Group			Production level in CF participants		
	Healthy (n = 10)	CF (n = 25)	p-value	No/low (<10 CFU) (n = 14)	High (≥ 10 CFU) (n = 11)	p-value
Participant characteristics						
Age, years, mean (SD)	37.3 (12.3)	33.3 (9.0)	0.29	36.7 (9.3)	28.9 (6.9)	0.029
Sex, male, n (%)	6 (60.0)	15 (60.0)	1.00	9 (64.3)	6 (54.5)	0.70
Body mass index (BMI), kg/m <sup>2</sup> , mean (SD)	24.6 (3.5)	22.8 (3.2)	0.14	22.5 (3.7)	23.1 (2.6)	0.63
FEV <sub>1</sub> % predicted, mean (SD)	92.6 (9.2)	53.8 (20.8)	<0.001	54.2 (23.2)	53.3 (18.2)	0.91
Mean <i>P. aeruginosa</i> sputum concentration, x 10 <sup>7</sup> CFU/mL (95% CI) <sup>a</sup>	n/a	5.2 (2.1 – 12.9)	-	1.9 (0.7 – 5.7)	18.3 (4.7 – 70.9)	0.008
Participants with <i>P. aeruginosa</i> detected in cough aerosols						
Uncovered cough test						
n (%)	n/a	20 (80.0)	-	9 (64.3)	11 (100.0)	
Mean CFU (95% CI) <sup>a</sup>		17 (7 - 43)		2 (1 – 4)	75 (34 – 165)	<0.001 <sup>d</sup>
Surgical mask tests						
10-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) <sup>a</sup>		4 (1 – 10)		1	5 (1 – 13)	
20-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) <sup>a</sup>		4 (1 – 10)		1	4 (1 – 11)	0.99 <sup>e</sup>
40-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) <sup>a</sup>		3 (1 – 7)		1	4 (1 – 9)	0.56 <sup>f</sup> , 0.64 <sup>g</sup>
N95 mask test <sup>~</sup>						
20-minutes total wear (n=23)						
n (%)	n/a	4 (17.4)	-	0 (0.0) <sup>b</sup>	4 (40.0) <sup>c</sup>	
Mean CFU (95% CI) <sup>a</sup>		2 (0 – 6)		n/a	2 (0 – 6)	0.19 <sup>h</sup>

203 *Definitions:* FEV<sub>1</sub>, forced expiratory volume in 1 second; CFU, colony forming unit; CFU/mL, CFU per millilitre of sputum; SD, standard deviation;  
204 CI, confidence interval, n/a, not applicable ~ Optional test  
205  
206 <sup>a</sup>geometric mean  
207 <sup>b</sup>participant number (n) = 13  
208 <sup>c</sup>participant number (n) = 10  
209 <sup>d</sup>Uncovered cough (geometric mean CFU) compared to each surgical mask test (geometric mean CFU)  
210 <sup>e</sup>Surgical masks (geometric mean CFU): 10-minutes *versus* 20-minutes total wear  
211 <sup>f</sup>Surgical masks (geometric mean CFU): 10-minutes *versus* 40-minutes total wear  
212 <sup>g</sup>Surgical masks (geometric mean CFU): 20-minutes *versus* 40-minutes total wear  
213 <sup>h</sup>Mean CFU surgical mask 20-minutes total wear *versus* mean CFU N95 mask 20-minutes total wear

214 Table 2: Summary of mask properties

Mask properties	Mask comfort			Mask weight change	
	Healthy n (%)	CF n (%)	p-value	All participants Median (IQR)	p-value
Uncovered cough comfort level			1.00	n/a	n/a
Poor	0 (0.0 %)	0 (0.0 %)			
Sufficient	1 (10.0 %)	2 (8.0 %)			
Good	9 (90.0 %)	23 (92.0 %)			
Coughing wearing a surgical mask – 10-minutes total wear			0.001	0.01g (0.00g – 0.02g)	n/a
Poor	1 (10.0 %)	0 (0.0 %)			
Sufficient	0 (0.0 %)	15 (60.0 %)			
Good	9 (90.0 %)	10 (40.0 %)			
Coughing wearing a surgical mask – 20-minutes total wear			0.007	0.01g (0.00g – 0.02g)	0.73 <sup>a</sup>
Poor	1 (10.0 %)	1 (4.0 %)			
Sufficient	0 (0.0 %)	13 (52.0 %)			
Good	9 (90.0 %)	11 (44.0 %)			
Coughing wearing a surgical mask – 40-minutes total wear			0.023	0.02g (0.01g – 0.03g)	0.25 <sup>b</sup> , 0.031 <sup>c</sup>
Poor	1 (10.0 %)	2 (8.0 %)			
Sufficient	1 (10.0 %)	15 (60.0 %)			
Good	8 (80.0 %)	8 (32.0 %)			
Coughing wearing N95 mask -20-minutes total wear			0.018	0.02g (0.00g – 0.04g)	0.21 <sup>d</sup>
Poor	0 (0.0 %)	11 (47.8 %)			
Sufficient	7 (77.8 %)	8 (34.8 %)			
Good	2 (22.2 %)	4 (17.4 %)			

215

216 <sup>a</sup>Surgical mask weight change: 10-minutes *versus* 20-minutes total wear

217 <sup>b</sup>Surgical mask weight change: 20-minutes *versus* 40-minutes total wear

218 <sup>c</sup>Surgical mask weight change: 10-minutes *versus* 40-minutes total wear

219 <sup>d</sup>Mask weight change after 20-minutes wear: surgical mask *versus* N95 mask

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